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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,719	11/17/2003	Janel E. Young	ETH5095	2358

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ROBERTS MLOTKOWSKI SAFRAN & COLE, P.C.
Intellectual Property Department
P.O. Box 10064
MCLEAN, VA 22102-8064

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

lgallaugher@rmsclaw.com
dbeltran@rmsclaw.com
bdiaz@rmsclaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/714,719	YOUNG ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of amenmdent and remnarks filed 8/14/09. Claims 1, 2, and 13 are amended. Claims 1-13 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adachi et al. ("The prevention of Postoperative Intraperitoneal adhesions by Tranilast: N-(3',4'-dimethoxycinnamoyl) Anthranilic Acid) in Jpn. J. of Surg., (1999), 29, 51-54) in view of Sheffield et al. (US 4,937,254) for reasons of record and with minor modification to address the amendment to claim 1.

4. Adachi describes how to prevent postoperative intraperitoneal adhesions by oral administration of composition comprising tranilast and carboxymethylcellulose prior to and after surgery (see the whole document with emphasis on the abstract and page 52). The carboxymethylcellulose meets the limitation of delivery vehicle of claim 1. Therapeutically effective amount as recited in claim 1 is any amount deemed effective by the artisan. Administration of 60 mg/kg per day represents a single dose as recited in claim 8 and also meets the limitation of claim 11. The carboxymethyl cellulose is a sustained release excipient so that the composition administered is in sustained release form meeting claims 9 and 10. The oral administration of tranilast composition prior to surgery meets the limitations of systemic administration and thus meets claims 12 and 13. The melted tranilast and the carboxymethylcellulose are in solution form so that the carrier composition in claim 3 is met.

5. Adachi does not teach that the composition comprising tranilast is locally administered to tissue at surgical sites to treat adhesions. But, local and/or topical administration of therapeutic agents at surgical sites to treat or inhibit adhesion formation is known for various agents. For example:

6. Sheffield discloses method of inhibiting the formation of post surgical adhesion by administration of compositions to the site of surgical trauma to inhibit the post surgical adhesion (abstract; column 2, lines 34-38; column 3, lines 15-28, 39-56). The composition locally or topically administered at the surgical site comprises non-steroidal anti-inflammatory drug (NSAID) and pharmaceutically acceptable carrier (column 4, lines 12-29); when the composition is carried in a liposome or when the NSAID is encapsulated in a microcapsule, the composition of Sheffield meets the requirements of claim 3; when the polymeric carrier is lactide, the

composition of Sheffield meets the requirements of claim 4. Furthermore, Sheffield teaches that the composition can be applied by catheterization using implanted osmotic pump (column 3, lines 29-38) so that when the delivery method is by osmotic pump, the requirement of claim 3 is met.

7. Therefore, taking the teachings of Adachi and Sheffield, one having ordinary skill in the art at the time the invention was made would have reasonably expectation of success that topical or oral administration anti-adhesion composition of Adachi or Sheffield or the combined composition of Adachi and Sheffield would produce the expected inhibition of post surgical adhesion.

8. When the composition of Adachi and Sheffield are combined, the composition having tranilast and anti-inflammatory agent meets claims 2, 5 and 6 with the topical administration meeting requirements of claim 2. With regards to claim 7, the basic structure of the analogs is related to the core structure of the tranilast so that it flows that the activities of the analogs and the tranilast would be the same.

9. The amendment to claim 1 requires the delivery vehicle to contain tranilast. The solution of Adachi contains carboxymethylcellulose and tranilast meeting the requirement of amended claim 1. The suitability of the delivery vehicle for use in the local and non-systemic administration in claim 2 is the property of the delivery vehicle.

Response to Arguments

10. Applicant's arguments filed 8/14/09 as they apply to the current rejections have been fully considered but they are not persuasive.

11. Applicant argues that Adachi fails to disclose or suggest local administration of a delivery vehicle containing tranilast onto said tissue surfaces at the surgical site.

12. While the examiner agrees with the applicant that Adachi does not teach local administration, the rejection is made under 35 USC 103 relying on a secondary reference that teaches that post surgical adhesions are treated by locally or topically administering composition to the surgical site.

13. Applicant argues that Sheffield is directed strictly to topical administration of NSAID for adhesion prevention and that NSAIDs are completely different class of pharmaceuticals as compared to tranilast so that one skilled in the art would not consider tranilast a substitute for NSAIDs whether the administration is topical or oral.

14. Applicant's arguments are not persuasive. The rejection is not one where substitution of one drug for another is advocated. Rather, because it is known in the art to topically administer compositions directly on to a surgical site for treating or preventing adhesion formation, it would be reasonable to expect that the topical or local administration of tranilast composition would be expected to effectively inhibit post adhesion formation. Further, the comprising language of the claims is open so that the combined composition of Adachi and Sheffield would also meet the limitation of the claimed composition topically applied to inhibit adhesion.

15. Applicant argues that the skilled artisan would not have been led to expect that every drug known to be efficacious when administered orally would be efficacious is administered topically. The examiner disagrees with applicant's analysis of the Adachi in view of Sheffield rejections. The issue is not that every drug would treat post operative adhesion. Rather, the Sheffield reference provides a teaching that post operative adhesion can be treated by topical or

local administration. Thus, the artisan at the time the invention was made would reasonably expect that topical or local administration of composition comprising tranilast would also be effective in treating post operative system; both references are in the same field of treating post operative adhesion; treatment of post operative adhesion is expected and anticipated and predictable.

16. While the examiner agrees with applicant that Sheffield does not teach tranilast, the examiner notes that Sheffield teaches method of inhibiting post surgical adhesion by locally administering composition to surgical site to inhibit the adhesion. Sheffield is relied upon for teaching that post surgical adhesion is inhibited by topical administration of compositions containing NSAID and carrier composition. Thus, post surgical adhesion is effectively treated by topical or oral administration according to Sheffield and Adachi.

17. Furthermore, applicant argues against the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

18. No claim is allowed.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618